ENVIRONMENTAL PROTECTION AGENCY

[OPTS-42026A; TSH FRL 2372-3]

4-Chlorobenzotrifluoride; Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Federal Register of November 8, 1982 (47 FR 50555), EPA announced a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of 4-chlorobenzotrifluoride (4-CBTF). This preliminary decision was made pending consideration of public comments on a testing proposal submitted to EPA by Occidental Chemical Corporation for 4-CBTF. On the basis of its review and consideration of public comments, the Agency finds no reason to alter its preliminary decision. The Agency has concluded that this testing program, which has been modified to respond to technical comments, will provide sufficient data to reasonably determine or to predict the health and environmental effects of 4-CBTF. Therefore, EPA has determined not to propose a section 4(a) rule to require environmental or health effects testing of 4-CBTF at this time.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

In a previous notice, which appeared in the Federal Register of November 8, 1982 (47 FR 50555), the Agency announced a preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of 4-chlorobenzotrifluoride (4-CBTF). This decision was based on the Agency's tentative acceptance of a comprehensive testing proposal submitted by the Occidental Chemical Corporation (Occidental).

A draft of the Occidental proposal, which contained many of the protocols, was included in the public record (docket number OPTS-42026). The Agency requested comments on both its tentative decision not to require testing of 4-CBTF and on the proposed testing scheme.

II. Summary of Testing Program

The Occidental proposal consists of tiered systems for testing both health and environmental effects, with lower tier tests acting as triggers to additional testing or as stop points following review of the data with EPA personnel. The health effects testing program is divided into four major testing segments: (1) Acute toxicity screen, which has already been completed, (2) base set of tests, (3) conditional tests, and (4) additional mammalian testing, with three full program reviews (December 1983, March 1984, and March 1985). The environmental effects testing is divided into: (1) screening tests (acute toxicity, physical/chemical properties), (2) base set of tests, and (3) conditional tests, with one full program review occurring in November 1983.

The Occidental testing program will develop base sets of data for both environmental and health effects. For environmental effects, the base set data are derived from complete and partial life cycle tests using *Daphnia* and fathead minnow respectively, bluegill flowthrough bioaccumulation tests, soil adsorption/desorption tests, volatilization from water and photolysis in water studies, and anaerobic and aerobic aquatic metabolism investigations. The complete and partial life cycle tests are already completed; the other studies are scheduled to be completed in August 1983. Atmospheric fate studies while considered to be part of the conditional testing set are scheduled to be done after completion of the base testing for environmental effects. For health effects, the base set data are derived from subchronic exposure studies, primary metabolic studies (already completed), and mutagenicity and cell transformation studies (to be completed in August, 1983). Occidental is proposing to conduct a new 90-day subchronic toxicity study (scheduled for completion by November, 1983) because the existing study did not include a dose level at which toxic effects were observed. After a review of results from the base set tests by Occidental and EPA personnel, a determination will be made if further studies are necessary, such as additional subchronic studies, metabolic, reproductive, and teratogenicity investigations. Depending on the outcome of the base set tests, other testing such as carcinogenicity or effects on benthic organisms also may need to be considered.

III. EPA's Response to Public Comment

The Agency received comments only from the Natural Resources Defense Council (NRDC) on EPA's proposed decision not to test 4-CBTF and on Occidental's proposed testing scheme for this chemical. NRDC's comments overall indicated that the scope of the testing program was comprehensive and should meet the needs of the Agency in characterizing potential adverse health or environmental effects resulting from exposure to 4-CBTF. However, NRDC raised various issues, both legal and scientific, about EPA's proposed decision and about the proposed testing program. NRDC's basic concerns, along with EPA's response to each, are summarized below.

A. Legal Concerns

NRDC criticized EPA's policy of accepting negotiated testing agreements in lieu of rulemaking to require testing under section 4 of TSCA, arguing that the "plain language" of TSCA mandates that testing of section 4(e) chemicals must be accomplished by rule. In addition, NRDC contended that negotiated testing has many procedural and legal deficiencies, particularly the lack of enforceability of negotiated testing agreements and their failure to trigger other statutory provisions that would trigger a section 4 rule.

EPA had previously addressed NRDC's general concerns about negotiated testing in a Federal Register notice issued on January 5, 1982 (47 FR 335) which discussed the negotiated testing program for alkyl phthalates. A more detailed analysis of NRDC's arguments is included in the public record of that action. As was indicated in that notice, EPA believes that neither TSCA nor its legislative history supports NRDC's contention that Congress believed that rules were the exclusive means for accomplishing testing. EPA believes that negotiated testing is consistent with the statutory purpose that adequate data on chemicals be expeditiously developed by the involved companies.

EPA agrees that negotiated testing is not legally enforceable. However, as the Agency has previously indicated, there are strong practical reasons to expect that in the vast majority of cases, the involved companies will live up to their agreements. Furthermore, the Agency disagrees with NRDC's contention that, if EPA should be forced to develop a rule after the failure of a negotiated program, the entire program would take substantially longer than if EPA had pursued rulemaking from the beginning.

Rather, EPA believes that it could conduct an expedited rulemaking which in many cases would not substantially lengthen the entire process.

NRDC is correct in asserting that acceptance of a negotiated testing program will not trigger certain other statutory provisions that would have been brought into play if the Agency proposed, and then promulgated, a testing rule for these substances. But EPA believes that NRDC has considerably exaggerated the practical impact of this difference. EPA agrees that a negotiated testing program does not trigger the obligation of a manufacturer of a new substance to a section 4 rule to submit test data under section 5(b)(1), and to delay manufacture. Nevertheless, that particular provision of section 5 is only applicable to rules for a chemical category under section 4 and therefore has no relevance to EPA's actions on 4-CBTF, a single chemical.

In addition, contrary to NRDC's claim, EPA has the same authority to disclose health and safety data generated from negotiated testing as it would if the testing were conducted under a rule. Section 14(b)(1)(A)(i) makes data from any health and safety study on a chemical in "commercial distribution" (which should include virtually all chemicals designated by the Interagency Testing Committee) releasable on the same basis as section 14(b)(1)(A)(ii) which relates to data developed as a result of a test rule.

EPA's position that negotiated testing is a legally sufficient alternative to section 4 rulemaking was examined by the General Accounting Office (GAO) during 1982. The GAO concluded that "neither section 4(a) nor 4(e) compels the promulgation of a test rule proceeding where adequate test data may be developed pursuant to voluntary testing agreements. We (GAO) further conclude that since voluntary testing agreements are consistent with the significant purposes of section 4, implied authority exists for EPA to negotiate such agreements." (GAO. 1982. EPA Implementation of Selected Aspects of the Toxic Substances Control Act. General Accounting Office. December 7, 1982. GAO/RCED-83-62. pp. 15.)

Based on the above, EPA continues to believe that, where appropriate testing is being undertaken, negotiated testing agreements are an appropriate alternative to expensive, time-consuming rulemaking under section 4 of TSCA.

B. Scientific Concerns

1. NRDC noted that EPA should reserve the right to require long-term, chronic effects testing of 4-CBTF as well as chronic effects testing by the inhalation route. NRDC also noted that inhalation is a significant route of exposure, because workers are most likely to be exposed in this manner.

The Agency believes that, for TSCA section 4 purposes, a properly conducted 90-day subchronic study generally can produce sufficient data to reasonably predict chronic effects (USEPA. 1979. Proceedings of the Workshop on Subchronic Toxicity Testing. Denver, Colorado, May 20-24, 1979. OPTS Environmental Protection Agency). If the data obtained from the oral 90-day subchronic study are inadequate to reasonably determine or predict the chronic effects of 4-CBTF, EPA reserves the right to require industry to perform any further tests it considers necessary, such as a two year, chronic study. In addition, the Agency has seen no data to suggest that any toxicity for 4-CBTF would be dependent upon the route of administration. If the data from the metabolism studies and the oral 90-day subchronic study indicate that the route of exposure influences the type of effects observed, EPA reserves the right to require additional testing of appropriate duration by other routes of administration.

2. NRDC commented that the hierarchical approach to mutagenicity testing with a determinative *in vivo* test should be dropped infavor of a complementary battery of tests.

Because of prior positive results in two mutagenicity tests (sister chromatid exchange and unscheduled DNA synthesis), Occidental will perform an additional battery of tests on 4-CBTF. These test results will be used to determine what further testing, if any, is needed for 4-CBTF, including long-term testing and tests for heritable mutation. The Agency's general approach for mutagenicity testing under TSCA is a combination of a battery and a hierarchical approach. The first level testing includes four or more assays for gene mutation and chromosomal aberrations. These test results lead to additional testing for both mutagenicity and oncogenicity. The second level of testing in the Agency's scheme is *in vivo* testing, specifically tests to determine if the test agent reaches germinal tissue. This is because in pursuing mutagenicity as an endpoint in and of itself, it is necessary to determine if the test agent reaches germinal tissue where it may induce heritable gene or chromosomal mutations. A negative result at this stage of testing does not mean that a chemical is not a hazard. It merely indicates there is not sufficient evidence that the chemical reaches germinal tissue to justify undertaking whole animal tests for heritable mutations such as the specific locus and heritable translocation tests. Depending upon results in the lower tier, the chemical may still be considered to be a potential carcinogen and possibly subject to carcinogenicity testing.

3. NRDC noted that the method of evaluating mutagenicity data should be detailed and presented for public review.

The Agency believes that its method of evaluating mutagenicity testing is detailed adequately in the TSCA Test Guidelines (NTIS PB 82-232984) and was presented for public review in that context as well as in the proposed notice not to require testing under section 4(a) for 4-CBTF that appeared in the Federal Register on November 8, 1982 (47 FR 50555). Specific criteria for what is a positive or a negative result in these tests are provided in the TSCA Test Guidelines. Suggested changes to these criteria should be made in the Annual Reveiw of Test Guidelines Process (47 FR 41857, September 22, 1982). In addition, Occidental in response to NRDC's comments has revised the testing program to reflect the fact that both *in vitro* and *in vivo* test results, together with mammalian test data and metabolic information, will be used to assess risk and the need for additional testing.

4. NRDC commented that metabolic studies are not fundamental to section 4 testing and should not be given precedence over more relevant tests.

The Agency has concluded that, although not recommended by the Interagency Testing Committee, metabolic studies may be important in applying toxicology test data to risk assessment and in making extrapolations from test animals to humans. Occidental is proposing to do a metabolic study as part of the base set of tests, but it is not giving this study greater weight than any other test. No study that EPA has concluded to be important in the evaluation of the effects of 4-CBTF is being negelected because of the metabolic testing being conducted by Occidental.

5. NRD commented that the octanol/water partition coefficient of 4-CBTF should be determined experimentally rather than estimated from water solubility.

In general the Agency has concluded that an estimate of the octanol/water partition coefficient is sufficient, because that number is used primarily to estimate bioconcentration potential. In the case of 4-CBTF an actual bioconcentration potential study that

will address the accuracy of the estimate is planned.

6. NRDC noted that atmospheric fate studies should be part of the base set rather than part of the conditional testing set.

In response to NRDC's comment, Occidental clarified its intention ot indicate that atmospheric fate testing will be a definite part of the testing scheme. These tests were only placed in the conditional testing set because they involved complex and sophisticated test methodologies and adequate lead time was required to establish the appropriate testing procedures.

7. NRDC noted that testing for acute and chronic environmental effects on birds and wild mammals should be included in the environmental effects testing. The Agency believes it is appropriate to defer a decision on avian testing until the laboratory animal studies have been completed. If adverse effects are observed at low dose levels in these investigations and there is a demonstrated potential for substantial bioiaccumulation, the Agency will consider the need to require additional testing on avian species. So far as effects on wild mammals are concerned, it is accepted scientific practice to conclude that the results of laboratory animal tests would generally be applicable to wild mammals. The Agency acknowledges, however, that these inferences must be treated on a chemcial-specific basis. In the event that data emerging from the 4–CBTF testing program indicates a need to reconsider this approach in the context, EPA intends to do so. However, the Agency sees no basis at the present time to require avian or wild mammal testing.

IV. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 [docket number OPTS–42026]. This record includes:

(1) **Federal Register** notice designating 4–CBTF to the priority list.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) **Federal Register** notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in Room E–107, 401 M St. SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: July 11, 1983.

William D. Ruckelshaus,

Administrator.

[FR Doc. 83–19287 Filed 7–15–83; 8:45 am]
BILLING CODE 6560–50–M